Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Une étude randomisée de phase II visant à évaluer la brachythérapie à haute débit de dose et la brachythérapie à faible débit de dose comme monothérapie dans le traitement du cancer de la prostate localisé
Protocole ID	PR.19
ClinicalTrials.gov ID	NCT02960087
Type(s) de cancer	Prostate
Phase	Phase II
Type étude	Traitement
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
Investigateur principal	Dr Éric Vigneault
Coordonnateur	Josée Allard 418-525-4444 poste 16730
Statut	Actif en recrutement
But étude	The purpose of this study is to evaluate the dose of High Dose Rate (HDR) brachytherapy chosen for this study as well as a commonly used alternate form of brachytherapy called low dose rate (or seed) brachytherapy. Investigators would like to understand how these treatments control the prostate cancer and look at their short and long term treatment related side effects.
Critères d'éligibilité	• Histologically confirmed adenocarcinoma of the prostate diagnosed within the last 9 months. Patients on active surveillance with evidence of disease progression are eligible to the protocol as long as they meet the eligibility criteria and have a recent prostate biopsy (within 9 months). • Patients with low or intermediate risk prostate cancer are eligible according to the following guidelines: • TNM classification: • Clinical stage T1-T2 and Gleason 6 and PSA <20 ng/mL (Low risk) • Clinical stage T1-T2 and Gleason 7 (3+4) and PSA < 15 ng/mL and ≤ 50% of positive cores (Intermediate risk) • Eastern Cooperative Oncology Group status 0-1. • Bone scan and pelvic CT scan/MRI within the last 6 months at the discretion of the treating physician. • Multiparametric MRI of prstate within last 6 months • Patient must be ≥ 18 years of age. • Judged to be medically fit for brachytherapy. • Prostate volume by Trans-rectal Ultrasound (TRUS) or Magnetic Resonance Imaging (MRI) ≤ 60 cc within the last 6 months. • American Urological Association (AUA) score ≤ 20 (alpha blockers allowed) within the last 4 weeks. • Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life questionnaires in either English or French. • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate. • Patients must be accessible for treatment and follow-up. Patients registered on this trial must be treated and followed at the participating centre. • In accordance with CCTG policy, protocol treatment is to begin within 8 weeks of patient randomization. • Patients must be willing to take precautions to prevent pregnancy while on study.

Critères d'exclusion	• Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, or other solid tumours curatively treated with no evidence of disease for ≥ 5 years. • Prior or current bleeding diathesis. • Previous androgen deprivation therapy (ADT). • Alpha-reductase inhibitors (ARIs) within 90 days of randomization. • Radical surgery for carcinoma of the prostate, prior pelvic radiation, prior chemotherapy for prostate cancer, prior TURP, prior cryosurgery of the prostate. • Evidence of metastatic disease (radiology investigations at the discretion of the treating physician). • Any serious active or co-morbid medical conditions, laboratory abnormality, psychiatric illness, active or uncontrolled infections, or serious illnesses or medical conditions that would prevent the patient from participating or to be managed according to the protocol (according to investigator's decision).